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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,068	12/08/2003	Thomas J. Maginot	22220-08641	6619

758 7590 09/01/2004

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/731,068	MAGINOT, THOMAS J.
	Examiner	Art Unit
	Paul B. Prebilic	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-263 is/are pending in the application.

4a) Of the above claim(s) 6-84 and 202-259 is/are withdrawn from consideration.

5)☒ Claim(s) 5 is/are allowed.

6)☒ Claim(s) 1-4,85-201 and 260-263 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/6/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 85-201, and 260-263, drawn to a medical method, classified in class 623, subclass 1.1.

II. Claims 6-16, 29-38, and 50-71, drawn to a graft assembly, classified in class 623, subclass 1.31.

III. Claims 17-28, 39-49, 72-84, and 202-259, drawn to a graft and delivery assembly, classified in class 623, subclass 1.23.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and (II or III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Groups II or III could be used in a different method of use such as in a process of bypassing an intestine, a lymph duct, or other tubular structure.

Inventions III and II are related as combination and subcombination, respectively. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other

combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination merely requires "a graft" (see claim 17) yet the subcombination requires "a graft having an orifice; and a plurality of arms extending away from said orifice of said graft" (see claim 6). The subcombination has separate utility such as in a blood treatment machine or in the intestines instead of the blood circulatory system.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Al Smith on August 26, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5, 85-201, and 260-263. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-84 and 202-259 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 260-263 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,599,313. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more detailed and limited, but the present claims are read on thereby. For this reason, the present claims are considered to be clearly obvious in view of the patented claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 96, and 126 are rejected under 35 U.S.C. 102(e) as anticipated by Wilk (US 5,287,861) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilk (US 5,287,861) in view of Leckrone (US 4,747,405).

Wilk teaches anastomotically connecting a blood-conveying conduit, in the form of a stent, to a blood vessel endoscopically (see Figure 4) even though Wilk does not call his surgical device an endoscope. Since the surgical device is able to detect the properties of the vessel and heart wall and display them on a monitor, it is the examiner's position that Wilk inherently discloses an endoscope and the step of endoscopically implanting a vascular graft, in the form of a stent; see also, Figures 3A to 3E and Figures 5A to 6C as well as columns 3 to 5.

Alternatively, if one does not consider the surgical device of Wilk to constitute an endoscope or the method involving endoscopic insertion, then one would interpret Wilk as failing to meet the claim language. However, Leckrone teaches that is was known to use endoscopes in similar procedures in order to adequately use tools within the body; see the abstract and column 6, line 63 to column 7, line 7. Therefore, it is the Examiner's position that it would have been prima fascia obvious to use an endoscope to endoscopically insert the stent of Wilk so that the process could be more accurately monitored.

With regard to claims 96 and 126 specifically, the Examiner asserts that the laparoscope is structurally identical to an endoscope for the purpose of interpreting claim language because the laparoscope is merely an endoscope used in a particular part of the body. There is no specific structure that would distinguish the laparoscope from the endoscope.

Claim 261 is rejected under 35 U.S.C. 102(e) as being anticipated by Wilk (US 5,261,861). Wilk anticipates the claim language where the medical instrument as

claimed is the catheter (20) of Wilk and the heart wall of Wilk is construed to be outside the blood vessel; see *supra*.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donaldson (US 2,935,068) in view of Leckrone (US 4,474,405). Donaldson discloses bypassing a portion of a diseased aorta, but fails to disclose doing so endoscopically or with an endoscope or laparoscope as claimed; see Figures 2 and 3 as well as column 5, line 67 to column 6, line 24. However, Leckrone teaches that it was known to use endoscopes in similar procedures in order to adequately non-invasively use tools within the body; see the abstract and column 6, line 63 to column 7, line 7. Therefore, it is the Examiner's position that it would have been prima fascia obvious to use an endoscope to endoscopically insert the anastomotic devices of Donaldson to the anastomosis site so that the process could be more accurately monitored and to avoid using the more invasive procedure of open surgery on all the operation sites.

Claims 3, 4, 93, 94, 108, 123, 124, 131-140, 149, 150, 152, 165, 166, 168, 181, 194, 195, and 197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donaldson and Leckrone as applied to claims 1 and 2 above, and further in view of Wilk (US 5,287,861). Donaldson fails to disclose advancing the graft through or inside a lumen to the anastomotic site as claimed. However, Wilk teaches that it was known to use catheters to advance grafts to the anastomosis site; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to advance the graft of Donaldson to the anastomosis site for the same reasons as Wilk and in order to have a less invasive procedure for the patient.

Claims 85-92, 95, 97-107, 109-122, 125, 127-130, 141-148, 151, 153-164, 167, 169-180,182-193, 196, 198-201, 260, and 262 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (US 5,287,861) alone. Wilk meets the claim language except fails to disclose removal of the catheter and then advancing the graft or stent containing catheter to the site as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have separate catheters for the cutting step and the graft insertion step because Applicants have not disclosed that doing such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well result in the same end orientation and would not sufficiently complicate the procedure. Therefore, it would have been an obvious matter of design choice to modify Wilk to obtain the invention as specified in the claims.

With regard to claim 98, the aortic attachment end and the other vessel attachment end is viewed as statements of intended use that only require that the prior art device be capable of being used as such. In the Examiner's view, the stent of Wilk is fully capable of being used to attach to an aorta or other vessel as claimed.

With regard to claims 260 and 262 specifically, the Examiner posits that going from the downstream of the location access would have been considered prima fascia obvious over Wilk and is only an adjustment based upon the situation where the occlusion (BL) could not be bypassed as shown in the figures of Wilk.

Allowable Subject Matter

Claim 5 is allowed over the prior art of record.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738